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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,534	03/11/2004	Michael J. Caplan	2002834-0223	8752

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EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,534	CAPLAN ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *1-30 and 38-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-37* is/are rejected.

7)☒ Claim(s) 31-36 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/20/04; 6/07/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Restriction Requirement

Applicant's election without traverse of Group 3, claims 31-37 in the reply filed on August 25, 2006 is acknowledged.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/20/2004 and 6/7/06 have been received and acknowledged.

Status of Claims

Claims 31-37 are elected and pending in this office action.

Claims 1-30 and 38-62 are withdrawn from examining as they are to a non-elected specie.

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/427696, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

The claims are to a curcuminoids and no priority is given to date 10/27/99.

Claim Objections

Claims 31 and 36 are objected to because of the following informalities: The abbreviations of CFTR, ER and DBHQ should be spelled out. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

I. Claim 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. In particular, Applicant has not provided a description of the structure of a representative number of derivative compounds nor a description of the chemical and/or physical characteristics of a representative number of compounds nor a description of how to obtain a representative number of specific compounds.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

One skilled in the art would not know what these curcumin enhancing agents are, furthermore, there is no description of the curcumin enhancing agent in the specification.

II. Claims 31-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for flavone, an isoflavone, a benzimidazolone, a benzoquinolizinium, a tetrahydrobenzothiophene, a benzofuran, a pyramidinetrione, a dihydropyridine and an anthraquinone in the first agent, and curcumin, demethoxycurcumin, bisdemethoxycurcumin and cyclocurcumin in the second agent, does not reasonably provide enablement for a composition comprising a wide variety of agents that are capable of increasing CFTR functional activity as in item (i) nor in item (ii). The specification does not enable any person skilled in the art to which it pertains,

or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

the quantity of experimentation necessary

The claim is directed to a composition having two agents (i) a first agent that increases cystic fibrosis transmembrane conductance (CFTR) functional activity (ii) that causes increased release of CFTR from the endoplasmic reticulum (ER). The quantity of experimentation needed is undue experimentation. One of skill in the art would first need to determine which of the numerous known agents should be used that will increase CFTR functional activity, in order to do this series of testing would be done to determine what agent will show increase activity of the CFTR in combination with the second agent a curcuminoid that will release the CFTR from the ER. For example *S*-

nitrosoglutathione (GSNO),Nphenyllanthranilic acid, 1-ethyl-2-benzimidazolone (see enclosed reference British J. of Pharmacology (2001) 132, 659-668) a list of other agents that are capable of increasing CFTR functional activity. Applicant has not shown a representative genus to claim such a breadth, as shown there are other numerous compounds/agents discovered and yet to be discovered that are capable of increasing functional activity of CFTR.

Next, Applicants, the use of a cucurminoid, in item (ii) one of skill in the art would first need to determine which of the numerous known and unknown cucurminoids should be used.

the presence or absence of working examples

The specification does not provide any guidance with respect to a composition comprising two agent. It is not clear whether the composition is contains both items (i) and (ii) as one component, or the composition is separate and in a combination.

the predictability or unpredictability of the art

One of skill in the art would first need to determine which of the numerous known agents should be used that will increase CFTR functional activity, in order to do this series of testing would be done to determine what agent will show increase activity of the CFTR in combination with the second agent a curcuminoid that will release the CFTR from the ER.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim (31) recites that at least one of the agents is a curcumin, but with dependent claims 35 and 36, the agents listed are not curcuminiod. Does that mean that there are more than one agents present in item (ii) of claim 31 or as a whole there are more than two agents present in the composition?

Claim 31 and 36 are vague and indefinite in the recitation of "CFTR" ,"ER" or DBHQ. The use of laboratory designations to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. This rejection can be obviated by amending the claims to specifically and uniquely identify CFTR/ER or DBHQ for example, spelling it out when first used.

Claim 31 recites the limitation "a composition comprising a first and a second agent". There is insufficient antecedent basis for this limitation in the specification.

The specification only teaches a composition comprising of one agent. (See specification experiments 1-15).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Krumahar US 6,534.

Krumahar, teaches a composition comprising a curcuminoid, (see abstract) and also (col. 4 lines 25+, col. 5 lines 35+) an isoflavone (see also col. 5, lines 35+). Treating inflammation – does not alter the compound nor the composition. The above reference discloses a curcuminoid and an isoflavone. Consequently, the reference anticipates the claimed invention defined in claims 31 and 35.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
11/7/06

11/13/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER